APPLICATION

FOR

UNITED STATES LETTERS PATENT

TO ALL WHOM IT MAY CONCERN;

BE IT KNOWN THAT WE, BRIAN R. WILL, have invented new and useful improvements in a

EYE FIXATION APPARATUS

Of which the following contains the specification.

Application prepared
and forwarded for filing by:

KURT M. RYLANDER
USPTO Registration 43,897
1014 Franklin Street, Suite 206
Vancouver, WA 98660

Attorney Docket No. WILB01

US PATENT APPLICATION
Docket: WILB01
Inventor: WILL, Brian R.

EYE FIXATION APPARATUS

FIELD OF THE INVENTION

The present invention relates to devices and methods for fixating eyes for ophthalmic surgery, and more particularly to eye fixation devices and methods using vacuum pressure for fixation for guiding a surgical tool or laser.

BACKGROUND

Ophthalmic surgery typically requires fixating the eye so that the eye is stabilized from movement during surgery. Articles and methods for fixating the eye are well known in the art. There are known annuli for fixating the eye which have soft, spreadable rings which spread to conform to the shape of the eye, and then vacuum pressure, usually in the form of suction, is applied. Known articles and methods typically involve a annulus which encircles the cornea, and which has an open bottom, through which vacuum pressure is exerted, sucking the eye globe conjunctiva and attached sclera into the bottom of the annulus, thus stabilizing the annulus on the eye. Among the know art are annuli which are hard and which have an exposed channel which contacts the eye. Vacuum pressure runs through that exposed channel, sucking the eye globe conjunctiva and attached sclera into the channel. This deforms the eye globe conjunctiva and attached sclera into the shape of the channel ring. Thus, if the fixation needs to be adjusted, a deformation ring still exists,

which the annulus naturally settles back down upon again. This interferes with the ability to adjust the fixation device in the event of improper alignment.

The following represents a list of known related art:

Reference:	Issued to:	Date of Issue:
U.S. Patent 6,342,053 B1	Berry	January 29, 2002
U.S. Patent 6,338,710 B1	Takahashi et al	January 15, 2002
U.S. Patent 6,254,595 B1	Juhasz et al	July 3, 2001
U.S. Patent 6,231,585 B1	Takahasi et al	May 15, 2001
U.S. Patent 6,099,541	Klopotek	August 8, 2000
U.S. Patent 6,071,295	Takahashi	June 6, 2000
U.S. Patent 6,030,398	Klopotek	February 29, 2000
U.S. Patent 5,820,624	Yavitz	October 13, 1998
U.S. Patent 5,817,115	Nigam	October 6, 1998
U.S. Patent 5,807,380	Dishler	September 15, 1998
U.S. Patent 5,695,492	Brown	December 9, 1997
U.S. Patent 5,649,922	Yavitz	July 22, 1997
U.S. Patent 5,601,548	Smith et al	February 11, 1997
U.S. Patent 5,586,980	Kremer et al	December 24, 1996
U.S. Patent 5,582,608	Brown	December 10, 1996
U.S. Patent 5,569,280	Kamerling	October 29, 1996
U.S. Patent 5,556,417	Sher	September 17, 1996
U.S. Patent 5,556,406	Gordon et al	September 17, 1996
U.S. Patent 5,336,215	Hsueh et al	August 9, 1994
U.S. Patent 5,171,254	Sher	December 15, 1992
U.S. Patent 5,108,412	Krumeich et al	April 28, 1992
U.S. Patent 5,092,863	Schanzlin	March 3, 1992
U.S. Patent 5,009,660	Clapham	April 23, 1991
U.S. Patent 4,905,711	Bennett et al	March 6, 1990
U.S. Patent 4,718,418	L'Esperance, Jr.	January 12, 1988

U.S. Patent 4,688,570	Kramer et al	August 25, 1987
U.S. Patent 4,173,980	Curtin	November 13, 1979
U.S. Patent 3,074,407	T.E. Moon et al	January 22, 1963
EP 0372127A1	L Esperance	June 13, 1990
U.S. Des. Patent 364,681	Livernois	November 28, 1995

The teachings of each of the above-listed citations (which does not itself incorporate essential material by reference) are herein incorporated by reference. None of the above inventions and patents, taken either singularly or in combination, is seen to describe the instant invention as claimed.

Thus, while the foregoing body of art indicates it to be well known to have an eye fixation devices for ophthalmic procedures, the art described above does not teach or suggest an eye fixation apparatus which has the following combination of desirable features: (1) functions without the need for a lid speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used in patients with "tight lids" which are common to some races; (2) multi-point fixation as opposed to two point fixation to the surface of the eye; (3) markedly decreased deformation of the eye; (4) significantly reduces elevation of intraocular pressure: (a) safer; (b) more comfortable; (c) improves accuracy in femtosecond procedures: (5) decreases trauma to ocular surface and conjunctiva; (6) easier to reposition on globe of the eye if initial ring position is not suitable: (7) X and Y adjustment allows for superior centration properties; and (8) fixation screw is superior to pincer type fixation: (a) smoother docking possible; and (b) less manual dexterity required.

SUMMARY AND ADVANTAGES

An eye fixation apparatus of the present invention includes an eye fixation portion with a contact portion, having criss-crossing channels, which goes upon the surface of an eyeball and encircles the cornea, a vacuum port in communication with the criss-crossing channels to exert vacuum pressure through the channels to pull the eyeball to the bottom, and adjustment arms An eye fixation apparatus can further be provided with an X-translation guide member adjustably moveable in the X-translation direction in relation to the eye fixation portion, a docking screw, and a Y-translation guide member adjustably moveable in the Y-translation direction in relation to the eye fixation portion.

The eye fixation apparatus of the present invention presents numerous advantages, including: (1) functions without the need for a lid speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used in patients with "tight lids" which are common to some races; (2) multi-point fixation as opposed to two point fixation to the surface of the eye; (3) markedly decreased deformation of the eye; (4) significantly reduces elevation of intraocular pressure: (a) safer; (b) more comfortable; (c) improves accuracy in femtosecond procedures: (5) decreases trauma to ocular surface and conjunctiva; (6) easier to reposition on globe of the eye if initial ring position is not suitable: (7) X and Y adjustment allows for superior centration properties; and (8) fixation screw is superior to pincer type fixation: (a) smoother docking possible; and (b) less manual dexterity required.

Additional advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by

practice of the invention. The advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims. Further benefits and advantages of the embodiments of the invention will become apparent from consideration of the following detailed description given with reference to the accompanying drawings, which specify and show preferred embodiments of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of an embodiment of the present invention

FIG. 2 displays a top down view illustrating the X-Y adjustment capability of an embodiment of the present invention.

FIG. 3 shows the bottom view of the eye fixation portion of the present invention.

FIG. 4 shows a side view of the eye fixation portion of the present invention.

FIG. 5 shows an exploded view of an embodiment of the present invention.

FIG. 6 shows a detail of Figure 5.

DETAILED DESCRIPTION

Before beginning a detailed description of the subject invention, mention of the following is in order. When appropriate, like reference materials and characters are used to designate identical, corresponding, or similar components in differing figure drawings. The figure drawings associated with this disclosure typically are not drawn with dimensional accuracy to scale, i.e., such drawings have been drafted with a focus on clarity of viewing and understanding rather than dimensional accuracy.

As shown in **FIGs. 1 and 5**, an eye fixation apparatus **10** is provided. Eye fixation apparatus **10** includes an eye fixation portion **12**, a vacuum port **18** connected to said eye fixation portion, and adjustment arms **20** connected to said eye fixation portion. As shown in **FIGs. 1, 2, and 5**, eye fixation apparatus **10** can further be provided with annular X-translation and Y-translation guide members **40, 60**.

As shown in **FIGs 3, 4, and 5**, eye fixation portion **12** is preferably a short toroidal cylinder, with a flat portion on the top **26**, and on the bottom provided with an annular convex contact portion **14** which is shaped to conform to the surface of the eye globe and to encircle the cornea. Contact portion **14** is provided with two or more criss-crossing channels **16**, exposed on the bottom, which are in communication with the vacuum port **18** for providing vacuum suction to the eye globe conjunctiva attached to the sclera. When placed on the eye, with the contact portion **14** contacting directly upon the eye and encircling the cornea, the criss-crossing channels **16** are upon the eye globe conjunctiva. Vacuum port **18** communicates with channels **16** such that vacuum pressure exerted at the vacuum port **18** creates vacuum pressure in the criss-crossing channels **16**, sucking the eye globe conjunctiva attached to the sclera flush against the contact portion **14**. This fixates the eye. The criss-crossing channels **16** work to oppose the suction created by each other, such that the eye glove conjunctiva attached to the sclera, is spread taut between the channels **16**, instead of being sucked upon into a particular channel. The criss-crossing channels **16** spread the pressure differential created by the vacuum across the eye globe creating a balanced substantially uniform pressure differential, thus avoiding deformation of the eye globe conjunctiva and sclera in the particular channel.

This allows the apparatus to be moved, if an incorrect alignment is made, by shutting off the vacuum pressure, moving the apparatus to the correct alignment, and reasserting the vacuum pressure.

Those skilled in the art will know that the criss-crossing channels **16** can be configured in many different ways to create a substantially uniform pressure differential across the contact portion **14** in relation to the eye globe. Criss-crossing channels can be configured as seen in **FIGs 3 and 4**. Criss-crossing channels can be configured as parallel radial grooves with cross channels forming a "train track" like design, as multiple radial grooves with cross channels, as multiple interlocking cross-crossing channels, etc., so long as the configuration allows the pressure differential to be spread substantially uniform across the contact portion in relation to the eye glob.

As shown in **FIGs. 1, 2, 3 and 5**, vacuum port **18** is a hollow tube extending from and through the eye fixation portion **12** and is in direct communication with the channels **16** which criss-cross the annular convex contact portion **14** of the eye fixation portion **12** such that vacuum pressure applied to said vacuum port **18** exerts vacuum pressure through such criss-crossing channels **16** to pull the eye globe conjunctiva attached to the sclera to the contact portion **14**.

As shown in **FIGs. 1, 2, and 5**, one or more adjustment arms **20** are provided on said eye fixation portion **12** so that the apparatus **10** can be moved without having to directly handle the eye fixation portion **12**. Adjustment arms **20** allow the operator to lift the eye fixation apparatus **10** to adjust the fixation to the eyeball.

As shown in **FIG. 5** (not shown in **FIG. 4**), eye fixation apparatus **10** can further be provided with first and second opposing X-translation raised lipped walls **24** on

opposite sides of the flat portion **26** on the circular end of the eye fixation portion **12**, for slidably interlocking with an X-translation guide member **40**.

As shown in **FIGs. 1, 2, and 5**, eye fixation apparatus **10** can further be provided with an X-translation adjustment apparatus saddle **22**. Saddle **22** preferably has four columns extending up from a base, the four columns defining two crossing pathways in which are mounted the X-translation adjustment apparatus **44**.

As shown in **FIGs. 5 and 6**, X-translation guide member **40** is provided with opposing first and second grooves **28** on opposite sides the circular bottom of said member, that match to and interlock with the first and second X-translation raised lipped walls **24**. X-translation guide member **40** has a flat portion on the top **56**, and is flat on the bottom, between the grooves **28**, to rest on the flat portion **26** of the eye fixation portion **12**. X-translation guide member grooves **28** fit with X-translation raised lipped walls **24**. X-translation guide member slides along flat portion **26** of the eye fixation portion **12**. X-translation guide member **40** has first and second Y-translation raised lipped opposing walls **54** on opposite sides of the flat portion **56** on the circular end of the X-translation guide member **40** for slidably interlocking with a Y-translation guide member **60**.

As shown in **FIGs. 1, 2 and 5**, the X-translation guide member **40** is preferably provided with an X-translation adjustment apparatus **44** which mounts on the X-translation adjustment saddle **22** to move the X-translation guide member **40** laterally back and forth in the positive X and negative X direction in relation to the eye fixation portion **12**. X-translation adjustment apparatus **44** includes a threaded rod **50**, having an end knob **46** on one end, which threads through an adjustment knob **48** that sits in

the X-translation adjustment saddle **22**, and into threaded aperture **50A** of X-translation guide member. Adjustment knob **48** is preferably a circular grooved nut with threads running through center. Adjustment knob **48** sits orthogonal to the X-translation guide member **40** within one of the crossing pathways defined on the X-translation adjustment saddle **22**. Threaded rod **50** sits within and runs transversely to the other crossing path of the saddle **22**, screwing through the adjustment knob **48**, and into the threaded aperture **50A**. Turning the adjustment knob **48** moves the X-translation guide member **40** in the positive X and negative X direction.

As shown in **FIGs. 1, 2, and 5,** X-translation guide member **40** can further be provided with a Y-translation adjustment apparatus saddle **52**. Y-translation adjustment apparatus saddle **52** is shaped and operates in the same manner as the X-translation adjustment apparatus saddle **22**. Y-translation adjustment apparatus **64** mounts in Y-translation adjustment apparatus saddle **52** in the same manner that the X-translation adjustment apparatus **44** mounts in the X-translation adjustment apparatus saddle **22**.

As shown in **FIGs. 5 and 6**, Y-translation guide member **60** is provided with opposing first and second grooves **28** on the bottom of said member that match to and interlock with the first and second Y-translation raised lipped walls **54** on X-translation guide member. Y-translation guide member **60**, between the grooves **28**, is flat on the bottom to rest on the flat portion **56** between the Y-translation raised lipped walls **54** on the X-translation guide member **40**. Y-translation guide member **60** slides along flat portion **56** of X-translation guide member **40**.

Y-translation guide member **60** is provided with a Y-translation adjustment apparatus **64** which mounts to and sits in the Y-translation adjustment saddle **52** to move the Y-translation guide member **60** laterally back and forth in the positive Y and negative Y direction. Y-translation adjustment apparatus **64** includes a threaded rod **70**, having an end knob **66** on one end, that threads through an adjustment knob **68** that sits in the Y-translation adjustment saddle **52**, and into a threaded aperture **70A** in the Y-translation guide member **60**. Adjustment knob **68** is preferably a radial circular grooved nut with threads running through center. Turning the adjustment knob **68** moves the Y-translation guide member in the positive Y and negative Y direction.

Those skilled in the art will know that the X-translation guide member **40** and the Y-translation guide member **60** can be configured to translate respectively in any nonparallel lateral direction with respect to each other.

Those skilled in the art will know that in alternative embodiments the Y-translation guide member **60** can easily be connected directly to the eye fixation portion **12**, without having an X-translation guide member **40**: Those skilled in the art will know that the eye fixation portion **10** can be used without X-translation member **40** or Y-translation member **60**.

As shown in **FIGs. 1, 2, and 5,** a docking screw **72**, threaded on one end screws through the Y-translation cutting guide member **60** for tightening the guide member against objects inserted into the cylindrical space formed by the eye fixation portion **12** and guide members **40**, **60**. Those skilled in the art will know that docking

screw can easily be placed in the eye fixation portion **12**, or the X-translation guide member **40**.

Apparatus parts can be made of steel, or titanium, or other metals of sufficient strength and sterilizability known to those skilled in the art. Parts can be machined, cast, and etching may be used. Parts can also be made of hard plastic with similar sterilaziblity, tensile strength, and ability to be machined, known to those skilled in the art. Plastic can be machined or injection molded.

In operation in one embodiment, the apparatus **10,** held by the adjustment arms **20,** is placed upon the surface of the eyeball, to encircle the cornea, with the contact portion **14** directly contacting the eye globe conjunctiva. A vacuum is turned on which creates a vacuum pressure differential through the vacuum port **18** and into the criss-crossing channels **16**. If the contact portion **14** placement is not aligned around the cornea, the vacuum is shut off, the apparatus **10** is moved in the globe, using the adjustment arms **20**, and the vacuum is reapplied. The user can check for proper centration of the cornea using either direct visualization, placement of a laser docking cone, or by placing a targeting eyepiece into the cylindrical space formed by the first and second annular guide members **40, 60**. The apparatus **10** can be used with an applanation lens for surgery. Alternatively, the apparatus **10** can be used for surgery without an applanation lens, where the operation requires fixating the cornea.

Those skilled in the art will recognize that numerous modifications and changes may be made to the preferred embodiment without departing from the scope of the claimed invention. It will, of course, be understood that modifications of the invention, in its various aspects, will be apparent to those skilled in the art, some

being apparent only after study, others being matters of routine mechanical, chemical and electronic design. No single feature, function or property of the preferred embodiment is essential. Other embodiments are possible, their specific designs depending upon the particular application. As such, the scope of the invention should not be limited by the particular embodiments herein described but should be defined only by the appended claims and equivalents thereof.